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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,923	07/19/2005	Cedric Szpirer	VANM290.001APC	6813

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
HILL, KEVIN KAI	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	03/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 03/29/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/507,923	SZPIRER ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 15-24 and 26-28, drawn to a recombinant cell or organism having incorporated into genome i) a genetic construct a nucleotide sequence encoding a toxic molecule, and ii) a genetic sequence encoding an antidote molecule to said toxic molecule.

Group II, Claims 15-28, drawn to a recombinant cell or organism having incorporated into genome i) a genetic construct a nucleotide sequence encoding a toxic molecule, ii) a genetic sequence encoding an antidote molecule to said toxic molecule, and iii) a genetic sequence which is the target of the toxic molecule.

Group III, Claims 29-33, drawn to a method of producing and selecting a genetically modified cell or organism.

2 The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c). "

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant application, the common technical feature as a whole is a recombinant cell or organism having incorporated into its genome a genetic construct encoding a toxic gene under the control of an inducible promoter and a genetic sequence encoding an antidote molecule to said toxic molecule with the condition that the sequence encoding the antidote molecule is not present natively in said cell or organism. However, Norris et al (U.S. Patent No. 6,271,359) disclose a genus of eukaryotic host cells (col. 30, lines 17-42) containing genetic systems to express a toxic gene product and an antidote gene product (col.s 8-18), wherein the genes are the control of inducible promoter systems (col.s 27-28). Thus, the instant invention does not contribute over the prior art. Furthermore, the special technical feature of Group II is a third genetic sequence that is or encodes a target of a toxic molecule.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. **Should Applicant elect any of Groups I-III, a further restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one biologically distinct organisms and structurally distinct genetic constructs. Furthermore, Applicant recites conditional language such as "optionally" and alternatives "or". These elements are deemed to lack unity of invention *a priori* because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In response to the restriction requirement, Applicant must further elect one of the alternative genetic constructs of Claim 15(i) that does, or does not, comprise a selectable marker.

In response to the restriction requirement, Applicant must further elect one of the alternative genetic constructs of Claim 15(ii) wherein the genetic construct that encodes the antidote.

In response to the restriction requirement, Applicant must further elect one of the toxic molecules of Claim 18.

In response to the restriction requirement, Applicant must further elect one biological organism, from the group of organisms consisting of a plant (Claims 19 and 31), an animal (Claim 20), a mammal (Claim 21), an insect (pg 6, [0029], line 6), or yeast (Claim 22).

In response to the restriction requirement, Applicant must further elect one of the alternatives regarding how organism is exposed to the non-toxic compound(s) (Claim 24).

In response to the restriction requirement, should Applicant elect the non-toxic compound to be synthesized by the organism, then Applicant must further elect one of the alternative tissues responsible for the synthesis (Claim 24).

In response to the restriction requirement, Applicant must further elect one of the alternative genetic sequences that is a target of the toxic molecule (Claim 25).

In response to the restriction requirement, Applicant must further elect one of the cell compartments comprising a genome within which the genetic construct is integrated (Claims 26-27), specifically a nucleus, a non-nuclear chloroplast organelle, or a non-nuclear mitochondrial organelle.

In response to the restriction requirement, Applicant must further elect one of the alternative genetic constructs of Claim 28, wherein the selectable marker is bordered by identical or different toxic genes.

Applicant is reminded that this is a restriction requirement and should not be construed as an election of species.

The embodiments listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the embodiments lack the same or corresponding special technical features for the following reasons:

The embodiments are drawn to multiple organismal and nucleic acid sequences that are structurally distinct, independent and mutually exclusive embodiment that yields distinctly different effects. The numerous variations in the number, position and type of nucleic acid sequences and the gene products encoded therein result in a vast genus of structurally unrelated molecules that are not obvious variations of each other. Each of the embodiments confers a unique, non-obvious, distinctly different technical feature onto the transgenic cell or organism that will directly impact toxicity or bioactivity of the gene products and are non-obvious variants because one of ordinary skill in the art would not expect an episomal genetic construct to be equivalent in stability and generational inheritance as a genetic construct that has integrated into the nuclear genome, for example. Similarly, an artisan would not expect ccdB to be identical in effect as Hok proteins. Applicants are reminded that nucleic acid sequences encoding different

proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Similarly, each transgenic organism is considered a distinct invention.

Given the breadth of the claimed, unrelated structures, a search for all possible embodiments imposes an exceptional burden on the Office. As the technical feature linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the embodiments does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named embodiment as listed in the cited claims to which the claims shall be restricted. The reply must also identify the claims readable on the elected embodiments, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Q. JANICE LI, M.D.
PRIMARY EXAMINER